

## ECHOGENIC SURFACE FOR ENHANCED ULTRASONIC VISIBILITY

### BACKGROUND OF THE INVENTION

#### Field of the Invention

[0001] The field of the invention relates generally to echogenic surfaces, and 5 more particularly, to echogenic surfaces for medical instruments, e.g., needles used in medical procedures, to enhance the ultrasonic visibility of the medical instruments.

#### Background

[0002] Needles are commonly used in various medical procedures, such as biopsy and amniocentesis procedures, to gain percutaneous access into the body. In a biopsy, for 10 example, a biopsy needle is inserted into the body to collect a tissue sample from a tumor. In amniocentesis, an aspiration needle is inserted into the amniotic sac to collect amniotic fluid.

[0003] These medical procedures are frequently monitored using an imaging technique. One widely used imaging technique is ultrasonography, which is commonly 15 used to image the development of a fetus. Ultrasonography relies on the “echogenicity” or ultrasonic visibility of organs and bones, and medical instruments placed inside the body. In a biopsy, ultrasonography is used to guide the biopsy needle to the tumor site. In amniocentesis, ultrasonography is used to guide the aspiration needle inside the amniotic sac to avoid injury to the fetus.

20 [0004] In order to guide a needle inside the body using ultrasonography, the needle must be visible in an ultrasound image. Unfortunately, the smooth cylindrical surface of a needle is very difficult to image using ultrasonography. FIG. 1 illustrates a

medical device 20 (e.g., a needle) of the prior art shows ultrasound waves 10 emitted from a transducer 15 striking the surface of the device 20. The device 20 reflects the ultrasound waves 10 in a direction 25 away from the transducer 15. As a result, the emitted ultrasound waves 10 are not returned to the transducer 15 and the device 20 is not 5 imaged.

[0005] To address this problem, various methods have been developed to enhance the “echogenicity” or ultrasonic visibility of a medical device, which problem can be worse for a thin device such as a needle. These methods typically involve providing a disrupted surface at the distal end or tip of the medical device or needle to enhance its 10 ultrasonic visibility. Current methods for providing disrupted surfaces on a needle include forming rings around the outer and/or inner cannula of the needle, sandblasting the needle surface, chemically etching the needle surface, drilling holes through the cannula of the needle, and coating the needle surface with a polymeric coating. The resulting disrupted surfaces enhance the ultrasonic visibility of the needle by isotropically 15 scattering incident ultrasonic waves. FIG. 2 illustrates an example of a prior art needle 30 with a disrupted surface 35 at its distal end. FIG. 2 shows ultrasound waves 10 emitted from a transducer 15 striking the disrupted surface 35 of the needle 30. The disrupted surface 35 reflects the ultrasound waves 10 in random directions 40 with some 20 of the waves being reflected back to the transducer 15 and some of the waves being reflected away from the transducer 15. The reflected waves received by the transducer 15 are used to create an ultrasound image of the needle.

[0006] Another method to enhance the ultrasonic visibility of a needle is to form dimples on the needle surface. FIG. 3A illustrates a side view of a prior art needle 50

with dimples 55 formed along its surface. FIG. 3B shows a radial cross sectional view of the prior art needle 50 of FIG. 3A. FIG. 3B shows ultrasound waves 65 striking one of the dimples 55 from a transducer 60. The dimples 55 reflect the ultrasound waves in different directions 70 with some of the waves being reflected back to the transducer 60 5 to form an ultrasound image and some of the waves being reflected away from the transducer 60.

[0007] Although the usefulness of etched, coated and sandblasted surfaces has been demonstrated, these disrupted surfaces typically have random disruptions that scatter incident ultrasound waves with no real direction. In addition, the dimples 55 only 10 direct ultrasound waves that are reflected off of a single point on its surface back to the transducer. The rest of the ultrasound waves are directed away from the transducer.

[0008] Therefore, there is a need for an echogenic surface that reflects more of the ultrasound waves back to the transducer. Such an echogenic surface would provide improved ultrasonic visibility of medical instruments, such as needles. This would make 15 it easier for physicians to guide the medical instruments inside the body using ultrasonography.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention. Moreover, in the 20 figures, like reference numerals designate corresponding parts throughout the different views. However, like parts do not always have like reference numerals. Moreover, all illustrations are intended to convey concepts, where relative sizes, shapes and other detailed attributes may be illustrated schematically rather than literally or precisely.

[0010] FIG. 1 is an illustration of a prior art needle having a smooth surface and shows ultrasound waves from a transducer striking the needle.

[0011] FIG. 2 is an illustration of a prior art needle having a disrupted surface at its distal end and shows ultrasound waves from a transducer striking the needle

5 [0012] FIG. 3A is a side view of a prior art needle with dimples formed along its surface.

[0013] FIG. 3B is a radial cross section of the prior art needle in FIG. 3A.

[0014] FIG. 4A is a schematic illustration of a side view of an improved medical device with concave slots formed on the surface of the needle.

10 [0015] FIG. 4B is a schematic illustration of a radial cross sectional view of the medical device in FIG. 4A.

[0016] FIG. 4C is a schematic illustration of an exploded side view of the medical device in FIG. 4A.

15 [0017] FIG. 5 is a schematic illustration of an example arrangement of concave slots formed on the surface of the improved medical device.

[0018] FIG. 6 is a schematic illustration of another example arrangement of concave slots formed on the surface of the improved medical device.

[0019] FIG. 7 is a schematic illustration of a radial cross sectional view of another example embodiment of an improved medical device having concave slots formed on the 20 surface of the medical device.

## **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

[0020] FIG. 4A is a schematic illustration of a side view of an improved medical device 110 with concave slots 115 formed on the surface 120 of the medical device 110. The improved medical device 110 may be any device intended for use within a human body such as a needle or catheter. In order to demonstrate an example, the improved medical device 110 may be referred to as a needle. However, references to any of the improved medical devices as a “needle” should not be construed to limit the medical device to needles.

[0021] The surface 120 may be made of the same or different material as the rest 10 of the improved medical device 110. The surface 120 may be, for example, stainless steel or plastic. The concave slots 115 preferably are located near or at the location of the improved medical device 110 which the physician desires to image. Thus, for a needle, the concave slots 115 may be located near the distal end or tip of the needle. The concave slots 115 may be formed on the surface 120 of the needle 110 using a variety of 15 techniques, including drilling, milling, etching, or pressing.

[0022] FIG. 4B is a schematic illustration of a radial cross sectional view of the improved medical device 110 of FIG. 4A. The surface of each concave slot 115 is substantially flat or straight 125 in the radial cross section. As shown in FIG. 4B, 20 ultrasound waves 130 strike the flat surface 125 of one of the concave slots 115 from a transducer 135 that is aligned with the flat surface 125. The ultrasound waves 130 are reflected off of the entire flat surface 125 of the concave slot 115 in a direction 140 back to the transducer 135. In contrast, the dimple 55 of the prior art only reflects ultrasound

waves off of a single point on its surface back to the transducer, with the rest of the ultrasound waves being reflected away from the transducer. Thus, the concave slots 115 of the improved medical device are able to reflect more of the ultrasound waves of the transducer 135 back to the transducer 135 than dimples 50, thereby providing a brighter 5 and less interrupted ultrasound image.

[0023] FIG. 4C is a schematic illustration of an exploded side view of the improved medical device 110 of FIGs. 4A and 4B. Each concave slot 115 has a curved surface 145 in the axial cross section. The curved surface 145 may be hemispherical, oval, or the like. The curved surface 145 of each concave slot 115 in the axial cross section enables the concave slot 115 to reflect “off axis” ultrasound waves 150 back to the transducer. The “off angle” ultrasound waves 150 are ultrasound waves that approach the concave slot 115 at an angle with respect to the axis 155 of the improved medical device 110. By increasing the curvature of the curved surface 145, each concave slot 115 is able to reflect “off axis” ultrasound waves 150 at more acute (i.e., steeper) angles with 10 respect to the axis 155 of the improved medical device 110. This feature is desirable when the transducer becomes orientated at an acute angle with respect to the axis 155 of the improved medical device 110, which can occur as the improved medical device 110 is 15 inserted deeper into a human body.

[0024] Therefore, the concave slot 115 of the improved medical device has a flat surface 125 in the radial cross section of the needle 110 and a curved surface 145 in the axial cross section of the needle 110. The flat surface 125 in the radial cross section 20 enables the concave slot 115 to reflect more of the ultrasound waves back to the

transducer, while the curved surface 145 in the axial cross section enables the concave slot 115 to reflect “off axis” ultrasound waves back to the transducer.

[0025] Referring to FIG. 4A, the concave slots 115 are arranged preferably along the entire circumference of the needle 110. This enables the needle 110 to be visualized 5 regardless of the rotational orientation of the needle 110 with respect to the transducer.

[0026] FIG. 5 is a schematic illustration of another example embodiment of the improved medical device 110 in which concave slots are arranged in a different pattern on the surface 120 of the improved medical device 110. Some of the concave slots 115 are orientated in the same direction as in the example embodiment illustrated in FIGs. 10 4A-4C, in which the concave slots 115 have a flat surface in the radial cross section and a curved surface in the axial cross section of the improved medical device 110. The rest of the concave slots 165, however, are orientated in a perpendicular direction, in which the surface of the concave slots 165 is flat in the axial cross section and curved in the radial cross section. By arranging the concave slots 115 and 165 in two different orientations 15 on the surface 110 of the improved medical device 110, the improved medical device 110 is able to reflect ultrasound waves from different angles of approach back to the transducer. This increases flexibility by allowing the improved medical device 110 to be visualized from different angles of entry into a body in relation to the transducer.

[0027] FIG. 6 is a schematic illustration of still another example arrangement of 20 the concave slots 115 and 165 on the surface of an improved medical device. The concave slots 115 and 165 may be arranged in a variety of patterns on the needle to achieve different image responses for the improved medical device. In addition, the

concave slots may be arranged in different orientations on the improved medical device other than those shown in FIGs. 5 and 6 to reflect ultrasound waves from various angles back to the transducer. In this case, the surface of each concave slot is flat in one cross section and curved in a perpendicular cross section.

5 [0028] FIG. 7 is a schematic illustration of a radial cross sectional view of yet another example of an improved medical device having concave slots 175. Each concave slot 175 has a bottom surface 180 that follows the contour of the surface of the improved medical device, such as a needle. In the example shown in FIG. 7, the bottom surface 180 of each concave slot 175 is convex to follow the cylindrical contour of the surface of 10 the improved medical device. Each concave slot 175 has curved side surfaces 185 on each end of the bottom surface 180. The curved side surfaces 185 reflect ultrasound waves back to the transducer when the ultrasound waves 190 approach the concave slot 175 from skewed (i.e., sideways) angles with respect to the concave slot 175. The curved side surfaces 185 may be concave, for example.

15 [0029] While various embodiments of the application have been described, it will be apparent to those of ordinary skill in the art that many more embodiments and implementations are possible that are within the scope of the subject invention. For example, each feature of one embodiment can be mixed and matched with other features shown in other embodiments. Additionally, the invention may be applied to the surface 20 of other medical instruments besides needles where it is desirable to enhance the ultrasonic visibility of such instruments. For example, the invention may be applied to the surface of a catheter to enhance the ultrasonic visibility of the catheter. Therefore, the

invention is not to be restricted or limited except in accordance with the following claims and their equivalents.